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| APPLICATION NO. | FILING DATE | FIRST-NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/065,854 | 11/26/2002 | Renuka Uppaluri | 122432 CIP | 3376 |

23413 7590 11/01/2006

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| EXAMINER |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

2624

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/065,854

Applicant(s)

UPPALURI ET AL.

Examiner

Patrick L. Edwards

Art Unit

2624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-19, 21, 22, 28-34, 37-48, 50, 51, 53, 55 and 58-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-19, 21, 22, 28-34, 37-48, 50, 51, 53, 55 and 58-61 is/are rejected.
- 7) ☒ Claim(s) 1-4, 6-19, 21, 22 and 58-61 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 2624

DETAILED ACTION

1. The response received on 15 September 2006 has been placed in the file and was considered by the examiner. An action on the merits follows.

Response to Arguments

2. The arguments filed on 15 September 2006 have been fully considered. A response to these arguments is provided below.

35 USC 112, Second Paragraph Rejections

Summary of Argument:

Claim 59 was previously rejected under 35 USC 112(2) as being indefinite for failing to point out and distinctly claim the subject matter that applicant regards as his invention. The claim was rejected because of an inconsistency between the claim and the specification.

Examiner's Response:

Applicant has amended claim 59 so that the limitation has support in the specification. The previous rejection is hereby withdrawn. A new 112(2) rejection will be provided below.

Prior Art Rejections

Summary of Argument:

Applicant has amended independent claim 1, and argues that the combination of Giger and Sones does not teach all the limitations of the now amended claim.

Examiner's Response:

Applicant's arguments have been fully considered but are unpersuasive. The amended claim 1 is still obvious in view of Giger and Sones. These references will be applied to the newly amended claims below.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-4, 6-19, 21, 22, and 58-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 1, the penultimate paragraph now recites the following:

Art Unit: 2624

employing a feature selection algorithm on the region of interest to sort through candidate features of the region of interest, classifying a candidate region of interest on each image, and subsequently combining results of all the computer aided processing operations.

The metes and bounds of this limitation are unclear. The “feature selection algorithm” is said to be employed to “sort through candidate features of the region of interest”. This implies that the region of interest has already been selected and that we are now looking for features within that region of interest. In other words, we would say that the region of interest has already been classified. So then how does this claim also require “classifying a candidate region of interest on each image”? Since the first part of this claim appears to imply that a region of interest has already been classified, this is inconsistent with the next clause of the paragraph.

In order to interpret this claim in an understandable manner for purposes of applying prior art, the examiner will interpret the claim such that the region of interest has already been classified as a region of interest by the time we begin to sort through candidate features on that region of interest. With this interpretation in mind, the examiner notes that the added limitation does very little—if any—to alter the scope of claim 1 from its previous state.

Claims 2-4, 6-19, 21, 22, and 58-61 are rejected because of their dependency on a rejected claim.

Claim Objections

5. The follow quotations of 37 CFR § 1.75(a) provides the basis of objection:
 - (a) The specification must conclude with a claim particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention or discovery.
6. Claim 1-4, 6-19, 21, 22, and 58-61 objected to under 37 CFR § 1.75(a) as failing to particularly point out and distinctly claim the subject matter which the applicant regards as his invention or discovery, and failing to conform to the invention as set forth in the remainder of the specification. The reasons for this objection are stated in the above claim rejection.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 2624

8. Claims 1-4, 6-8, 13-19, 29-32, 34, 42, 45, 53, 55, 58, and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giger et al. (PN 6,205,348) in view of Sones et al. (PN 4,792,900). (hereinafter Giger and Sones respectively)

Regarding Claim 1: Giger discloses a method for computer aided processing of dual or multiple energy images acquired using an X-ray source, the method comprising:

- employing a data source, the data source including a dual or multiple energy image set including a high energy image, a low energy image, a bone image, and a soft tissue image, each member of the image set being available for processing along with each other member of the image set [Figure 22 illustrates two methods of obtaining dual energy radiographic images (col. 7 lines 47-51). The processing circuit receives dual energy images including high energy images, low energy images, “bone-cancelled” (soft-tissue) images, and “soft-tissue-cancelled” (bone) images (col. 7 lines 43-51). Giger discloses digitizing and storing into memory each acquired bone image, which are the low-energy and high-energy images (col. 10 lines 24-30). As shown in Figures 19 and 28, the image acquisition is coupled with a memory. As explained above in the response to arguments, the examiner concludes that because the low-energy and high-energy images are stored this makes them available for processing along with each of the other images in the claimed image set.];
- defining a region of interest within an image from the dual or multiple energy image set [Figure 23B. A region of interest (ROI) is selected for both the high energy and low energy images (col. 8 lines 65-67).];
- extracting a set of feature measures from the region of interest [Figure 23B. A measure related to bone mass is calculated for each image (col. 8 line 67 – col. 9 line 3).]; and,
- reporting the feature measures on the region of interest [Figure 28. The results are superimposed onto the images (col. 10 lines 46-47).].

Giger also discloses employing a data source including a dual or multiple energy image set. Giger does not disclose the image set being arranged to allow the computer aided processing to be performed once by incorporating features from all images of the image set. However, Sones discloses a diagnostic scanner (Figure 1, A) for obtaining a high energy image (Figure 1, V) and low energy image (Figure 1, U). As shown in Figure 1, these images are stored separately. Then from these images a soft tissue image (col. 6 lines 25-29) and a bone image (col. 7 lines 30-33) are formed and stored in separate memories (Figure 1, 42 and 52 respectively).

Therefore, Sones teaches separating out images (such as the images discloses in Giger) from each other such that all of the images of an image set are available for computer aided processing. It would have been obvious to one of ordinary skill in the art to modify Giger with Sones to capture and store both the low energy image and high

Art Unit: 2624

energy image and to create and store a soft tissue image and bone image, such that the image set is available for processing at the data source. In this manner, the diagnostic procedures of Giger would then just access the desired image from the respective memory. One would have been motivated to make this modification because it may be desirable to look back at the original unprocessed images. Additionally, it would have been desired to have the image set available in case the diagnostic procedures failed or were ruled inaccurate. In this case, the image set could be used again or by another diagnostic procedure to confirm the results of the initial diagnosis.

Regarding Claims 2: Giger discloses the method of claim 1 further comprising acquiring the image set using projection x-ray radiographic imaging [Figure 1. The first step is the acquisition of a radiographic image (col. 4 lines 4-5). Projection x-ray radiographic imaging is a well-known type of radiographic imaging and therefore it would have been obvious to one of ordinary skill in the art to acquire images in this manner.]. The analogous arguments of claim 2 are applicable to claim 24.

Regarding Claims 3: Giger discloses the method of claim 1 further comprising acquiring the image set using x-ray computed tomography (CT) wherein the dual or multiple energy CT acquisition enables computer aided discrimination between different tissue types of differing densities from different regions of an imaged object [Figure 1. The first step is the acquisition of a radiographic image (col. 4 lines 4-5). Computed tomography is a well-known type of radiographic imaging and therefore it would have been obvious to one of ordinary skill in the art to acquire images in this manner. Giger teaches an ANN circuit, which is a computer aided method for discriminating different regions (col. 11 lines 28-39).].

Regarding Claims 4: Giger discloses the method of claim 1 further comprising acquiring the image set using digital x-ray tomosynthesis [Figure 1. The first step is the acquisition of a radiographic image (col. 4 lines 4-5). Digital x-ray tomosynthesis is a well-known type of radiographic imaging and therefore it would have been obvious to one of ordinary skill in the art to acquire images in this manner.].

Regarding Claim 6: Giger discloses the method of claim 5 further comprising incorporating prior knowledge from training for classifying the region of interest [The artificial neural network was trained using prior knowledge of 43 cases to classify regions of interest (col. 11 lines 35-38).].

Regarding Claim 7: Giger discloses the method of claim 6 wherein incorporating prior knowledge from training includes computing features on known samples of different normal and pathological medical conditions [The artificial neural network learns from the features of known examples (col. 11 lines 42-47).].

Regarding Claim 8: Giger discloses the method of claim 7 wherein the feature selection algorithm sorts through the features of known samples, selects useful features of known samples, and discards features of known samples which do not provide useful information [The artificial neural network utilizes threshold values to discard features which produce outputs different from the desired results (col. 11 line 65 – col. 12 line 13).].

Art Unit: 2624

Regarding Claim 13: Giger discloses the method of claim 5 wherein classifying the region of interest using the optimal set of features comprises classifying one or more medical conditions [The artificial neural network uses the features to classify the bone as being osteoporotic or normal (col. 11 lines 37-38).].

Regarding Claim 14: Giger discloses the method of claim 5 wherein the data source further includes at least one of image acquisition system information and demographic information, symptoms, and history of patient, wherein the image acquisition system information, demographic information, symptoms, and history of patient serve as feature measures in the feature extraction algorithm [Image acquisition information, such as scatter radiation, and patient history, such as patient body size, are examples of feature measures used to calculate the bone mass (col. 8 line 67 – col. 9 line 3).].

Regarding Claim 15: Giger discloses the method of claim 1 further comprising detecting and diagnosing at least one medical condition [Figure 28 shows the detecting and diagnosing of the risk of future bone fracture (col. 10 lines 42-45).].

Regarding Claim 16: Giger discloses the method of claim 1 wherein defining a region of interest comprises manually selecting a region of interest [It is well known in the art of medical image processing to allow an expert to define the region of interest manually.].

Regarding Claim 17: Giger discloses the method of claim 1 wherein defining a region of interest comprises utilizing an automated algorithm [Figure 28. The selection of a region of interest is done by a circuit and therefore is an automated process (col. 10 lines 30-31).].

Regarding Claim 18: Giger discloses the method of claim 17 wherein utilizing an automated algorithm includes inputting user specifications [The user specifies the placement of a 64x64 pixel ROI (col. 4 lines 20-28).].

Regarding Claim 19: Giger discloses the method of claim 1 comprising defining regions of interest and incorporating features from all regions of interest on all images [The examiner takes official notice that it would be obvious to one of ordinary skill in the art to define regions of interest in each of the already obtained images and that the features would be incorporated in each image. One of ordinary skill would be motivated to annotate each image to simplify the display for analysis by a user thereby expediting the diagnostic process.].

Regarding Claim 29: The analogous arguments of claim 2 are applicable to claim 29.

Regarding Claim 30: The analogous arguments of claim 3 are applicable to claim 30. It is inherent in a computed tomography system that the detector generates a plurality of first images and a plurality of second images taken of the structure at different angles.

Art Unit: 2624

Regarding Claim 31: The analogous arguments of claim 3 are applicable to claim 31. It is inherent that a computer tomography system used for acquiring a dual energy system, specifically acquire a plurality of high energy images and a plurality of low energy images.

Regarding Claim 32: The analogous arguments of claim 4 are applicable to claim 32. It is inherent in a tomosynthesis system that the detector generates a plurality of first images and a plurality of second images taken of the structure at different angles.

Regarding Claim 34: Giger discloses a method for detecting bone fractures, erosions, calcifications or metastases, the method comprising:

- employing a data source, the data source including a dual or multiple energy image set, the image set comprising a high energy image, a low energy image, a bone image, and a soft tissue image [Figure 22 illustrates two methods of obtaining dual energy radiographic images (col. 7 lines 47-51).];
- utilizing a bone image from a dual or multiple energy image set [Figure 28. The radiographic images, which include a bone image or “soft-tissue-cancelled” image, is input via the image acquisition device (col. 10 lines 24-28).];
- selecting a region of interest within the bone image to search for a calcification, fracture or metastatic bone lesion [Figure 28. The region of interest is selected to ultimately determine the risk of future fracture (col. 10 line 46).];
- segmenting bone from a background of the bone image [Figure 28. The weighted sum circuit is used to segment the bone from a background to produce a bone-only image (col. 10 line 36 and col. 9 lines 47-52).]; and,
- identifying a candidate region within the bone as a candidate for a calcification, fracture or metastatic bone lesion [Figure 28. The ANN uses measures of bone mass and bone structure to determine a candidate for fracture (col. 10 lines 42-44).].

Regarding Claim 42: Giger discloses the method of claim 34 wherein identifying a candidate region comprises utilizing an edge detection algorithm [The edges of a vertebral body are detected to locate the ROI (col. 9 lines 59-61).].

Regarding Claim 45: Giger discloses the method of claim 34 further comprising indicating candidate regions on a display (col. 10 lines 48-50).].

Art Unit: 2624

Regarding Claim 53: The analogous arguments of claim 3, which includes the limitations of claim 1, are applicable to claim 53. Cone-beam computed tomography is a well-known type of radiographic imaging and therefore it would have been obvious to one of ordinary skill in the art to acquire images in this manner.

Regarding Claims 55: The analogous arguments of claim 4, which includes the limitations of claim 1, are applicable to claim 55.

Regarding Claim 58: Cone-beam computed tomography is a well-known type of radiographic imaging and therefore it would have been obvious to one of ordinary skill in the art to acquire images in this manner.

Regarding Claim 60: See the analogous arguments of claim 8.

9. Claims 9-12, 21, 22, 28, 33, 37-41, 43, 44, 46, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giger in view of Sones and further in view of Nishikawa et al. (PN 6,058,322). (hereinafter Nishikawa).

Regarding Claim 9: Giger discloses the method of claim 7, but does not disclose determining a feature measure's ability. However, Nishikawa discloses a method wherein the feature selection algorithm comprises determining a feature measure's ability to separate regions into different classification groups [The ANN determines a confidence rating indicating a feature measure's ability to correctly classify candidates as abnormal or normal (col. 31 lines 4-9)]. It would be obvious to one of ordinary skill in the art to modify Giger's ANN with Nishikawa's ANN to determine confidence ratings because both networks are used to classify candidates. Furthermore, one would be motivated to make this modification to determine classifications based on more accurate features.

Regarding Claim 10: Nishikawa discloses the method of claim 9 wherein the feature selection algorithm further comprises ranking each feature measure in the set of feature measures based on each feature measure's ability to separate regions into a classification group [The ANN ranks each feature measure based on confidence ratings (col. 31 lines 6-12)].

Regarding Claim 11: Nishikawa discloses the method of claim 10 wherein the feature selection algorithm further comprises reducing quantity of feature measures by eliminating correlated features [The examiner takes official notice that one of ordinary skill in the art would modify the ANN to eliminate correlated feature measures to reduce the number of calculations made by the ANN thereby decreasing processing time.]

Regarding Claim 12: Nishikawa discloses the method of claim 10 wherein the feature selection algorithm further comprises selecting highest ranked feature measure and adding additional feature measures in descending order [The ANN outputs the ranked order of the likelihood of malignancy (col. 32 lines 61-63)].

Art Unit: 2624

Regarding Claim 21: Nishikawa discloses the method of claim 1 wherein reporting at least one of the feature measures comprises using a marker on a display of each image within the dual or multiple energy image set where the at least one classified region is located [Figure 30. The arrows (740 and 750) act as markers on the display to indicate classified region of interest (col. 37 lines 41-47).]. It would be obvious to one of ordinary skill in the art to modify Giger's display of results to include markers as done by Nishikawa. Furthermore, one would be motivated to make this modification to distinguish regions of interest, especially when there is more than one region of interest in a single image.

Regarding Claim 22: Nishikawa discloses the method of claim 21 further comprising displaying a single image which incorporates all markers from each image within the dual or multiple energy image set [Figure 30. Four views (700, 710, 720, and 730) having markers from each image (740 and 750) are displayed in a single image (200) (col. 37 lines 34-47).].

Regarding Claim 28: Giger discloses a system for computer aided processing of dual energy images acquired using an X-ray source, the system comprising:

- detection means for generating a first image representative of photons at a first energy level passing through a structure and a second image representative of photons at a second energy level passing through the structure [Figure 22. The two detectors absorb photons having different levels of energy (col. 8 lines 47-51) and therefore obtain dual energy radiographic images (col. 7 lines 47-51).];
- storage means for storing the first image and the second image [Figure 28. The image acquisition device obtains the images and inputs them to memory (col. 10 lines 24-28).];
- processing means for: processing a dual energy image set including a bone image, a soft tissue image, a high energy image, and a low energy image from the first image and the second image [Figures 22 and 28. The memory is connected, via the image acquisition device, to the processing circuit, which begins with the ROI selection circuit (col. 10, lines 24-31). The processing circuit receives dual energy images including high energy images, low energy images, "bone-cancelled" (soft-tissue) images, and "soft-tissue-cancelled" (bone) images (col. 7 lines 43-51).];
- storing the dual energy image set in the memory as a data source [Inputting the images into memory reads on storing to memory (col. 10 lines 27-28).];
- defining a region of interest within an image from the dual energy image set [See analogous arguments in claim 1.];
- extracting a set of feature measures from the region of interest [See analogous arguments in claim 1.];

Art Unit: 2624

- employing a feature selection algorithm on the set of feature measures and identifying an optimal set of features [See analogous arguments in claim 8.];

Giger also discloses employing a data source including a dual or multiple energy image set. Giger does not disclose the image set being arranged to allow the computer aided processing to be performed once by incorporating features from all images of the image set. However, Sones discloses a diagnostic scanner (Figure 1, A) for obtaining a high energy image (Figure 1, V) and low energy image (Figure 1, U). As shown in Figure 1, these images are stored separately. Then from these images a soft tissue image (col. 6 lines 25-29) and a bone image (col. 7 lines 30-33) are formed and stored in separate memories (Figure 1, 42 and 52 respectively). Therefore, Sones teaches that all four images of the image set are available for computer aided processing. It would have been obvious to one of ordinary skill in the art to modify Giger with Sones to capture and store both the low energy image and high energy image and to create and store a soft tissue image and bone image, such that the image set is available for processing at the data source. In this manner, the diagnostic procedures of Giger would then just access the desired image from the respective memory. One would have been motivated to make this modification because it may be desirable to look back at the original unprocessed images. Additionally, it would have been desired to have the image set available in case the diagnostic procedures failed or were ruled inaccurate. In this case, the image set could be used again or by another diagnostic procedure to confirm the results of the initial diagnosis.

Giger also doesn't disclose the remaining steps of classifying, incorporating, or displaying. However Nishikawa does disclose a system for processing dual energy images comprising:

- classifying the optimal set of features [See analogous arguments in claim 9.]; and,
- incorporating prior knowledge from training into classifying the optimal set of features [By providing ratings for each feature measure, the ANN is in essence classifying them. These ratings are assigned utilizing prior knowledge of ratings that observers have given to actual cases (col. 30 lines 55-60).]; and,
- display means for displaying at least one classified region of interest [Figures 31 and 32 display ROIs classified as containing microcalcifications and/or masses (col. 37 lines 48-52).].

It would have been obvious to one of ordinary skill in the art to modify Giger's ANN with Nishikawa ANN because both are used for automated diagnosis using medical images. Furthermore, one would have been motivated to modify Giger with Nishikawa to use give more weight to those features that are deemed more important in the diagnosis process.

Regarding Claim 33: Giger discloses a storage medium encoded with a machine readable computer program code, said code including instructions for causing a computer to implement a method for aiding in processing of dual or multiple energy images, the method comprising:

Art Unit: 2624

- employing a data source, the data source including a dual or multiple energy image set having a first decomposed image, a second decomposed image, a high energy image, and a low energy image [See analogous arguments in claim 1.];
- defining a region of interest within an image from the dual or multiple energy image set [See analogous arguments in claim 1.];
- extracting a set of feature measures from the region of interest [See analogous arguments in claim 1.]; and,
- employing a feature extraction algorithm on the feature measures for identifying an optimal set of features [See analogous arguments in claim 8.].

Giger also discloses employing a data source including a dual or multiple energy image set. Giger does not disclose the image set being arranged to allow the computer aided processing to be performed once by incorporating features from all images of the image set. However, Sones discloses a diagnostic scanner (Figure 1, A) for obtaining a high energy image (Figure 1, V) and low energy image (Figure 1, U). As shown in Figure 1, these images are stored separately. Then from these images a soft tissue image (col. 6 lines 25-29) and a bone image (col. 7 lines 30-33) are formed and stored in separate memories (Figure 1, 42 and 52 respectively). Therefore, Sones teaches that all four images of the image set are available for computer aided processing. It would have been obvious to one of ordinary skill in the art to modify Giger with Sones to capture and store both the low energy image and high energy image and to create and store a soft tissue image and bone image, such that the image set is available for processing at the data source. In this manner, the diagnostic procedures of Giger would then just access the desired image from the respective memory. One would have been motivated to make this modification because it may be desirable to look back at the original unprocessed images. Additionally, it would have been desired to have the image set available in case the diagnostic procedures failed or were ruled inaccurate. In this case, the image set could be used again or by another diagnostic procedure to confirm the results of the initial diagnosis.

It would have been obvious to one of ordinary skill in the art to modify Giger's ANN with Nishikawa's ANN to determine confidence ratings because both networks are used to classify candidates. Furthermore, one would have been motivated to make this modification to determine classifications based on more accurate features.

Regarding Claim 37: Giger discloses the method of claim 36 wherein rules are based on size measurements of line edges of the identified candidate regions [Surface area is calculated for each ROI and used to determine the classification (col. 11 lines 5-9).].

Regarding Claim 38: Giger discloses the method of claim 34, including segmenting bone from a background image. Giger does not disclose the segmentation using a region growing algorithm. However, Nishikawa discloses the segmentation wherein segmenting bone comprises utilizing a region growing algorithm [Figure 5. Region growing

Art Unit: 2624

is used to delineate a microcalcification from an ROI (col. 9 lines 29-34).]. It would be obvious to one of ordinary skill in the art to modify Giger's segmentation with Nishikawa's segmentation to include a region growing algorithm to more accurately identify a bone-only image from the background.

Regarding Claim 39: Nishikawa's the method of claim 38 wherein the region growing algorithm is manually initialized by having a user select a seed point [The examiner takes official notice that it would be obvious to one of ordinary skill in the art to initialize the region growing algorithm with a user selected seed point.].

Regarding Claim 40: Nishikawa discloses the method of claim 38 wherein the region growing algorithm is automatically initialized by utilizing bone attributes to select a seed point [The examiner takes official notice that it would be obvious to one of ordinary skill in the art to initialize the region growing algorithm with an automatically selected seed point.].

Regarding Claim 41: Giger discloses the method of claim 34, but does not disclose multi-level intensity thresholding. However, Nishikawa discloses bone segmentation wherein segmenting bone comprises multi-level intensity thresholding [Figure 5. A rough threshold is used first followed by a precise threshold (col. 9 lines 29-34).]. It would be obvious to one of ordinary skill in the art to modify Giger's bone segmentation with Nishikawa's multi-level intensity thresholding to correct a bias formed by residual background variation (col. 9 lines 35-39).]

Regarding Claim 43: Giger discloses the method of claim 42, but does not explicitly disclose using morphological erosion. However, Nishikawa discloses a method of detecting microcalcifications wherein image processing using morphological erosion is used for eliminating noise and false edges [Morphological erosion is used to shrink the object thereby removing noise and false edges (col. 18 lines 42-43).] It would be obvious to one of ordinary skill in the art to modify Giger's combination of weighted summation and integration methods, used to reduce the number of false edges and noise in the ROI (col. 9 lines 48-61), with morphological erosion as taught by Nishikawa instead of the.

Regarding Claim 44: The method of claim 42 wherein rib edges are eliminated using a connectivity algorithm [The morphological erosion method as explained in claim 29 is used in conjunction with a morphological dilation operator to remove false positives (col. 18 lines 35-55). It is well known that rib edges yield false positives in chest images and therefore would be identified and eliminated by the combination of these processes.]

Regarding Claim 46: Giger discloses the method of claim 45, but does not disclose placing markers on the bone image. However, Nishikawa discloses at method for detecting microcalcifications wherein indicating candidate regions comprises placing a marker on the bone image indicative of a classification of the candidate region [Figure 30. Markers (740 and 750) are placed on the classified regions of interest (col. 37 lines 34-47).]. It would be obvious to one of ordinary skill in the art to modify Giger with Nishikawa's markers to help an observer better understand the results.

Art Unit: 2624

Regarding Claim 59: Giger discloses the method of claim 1, wherein the feature selection algorithm calculates a bone mass and uses an ANN to interpret the features (col. 8 line 67 – col. 9 line 3 and col. 10 lines 46-47). Giger does not disclose reducing the feature measures, ranking the feature measures, or selecting the ranked features. However, Nishikawa discloses an artificial neural network (ANN), which extracts features for classification, comprising the steps of:

- reducing a quantity of feature measures (inputs) by eliminating correlated features, thereby eliminating extra features that provide the same information as other features, resulting in a reduced set of feature measures [Nishikawa discloses that 10 of the 26 inputs are clinical parameters, which are feature measures corresponding to patient information. The remaining 16 inputs are radiological findings, which means each type of patient information (i.e. age, sex, etc.) is input just once into the ANN. Although, no correlation is expressly disclosed it would have been obvious to one of ordinary skill in the art to modify Giger's ANN to only accept one input for each type of patient information shared by each image in the image set disclosed by Sones. For example, it is obvious that the patient's age for each of the images in the image set disclosed by Sones would be the same. Therefore, only one input for the patient's age would be used in Giger's ANN. So, although a correlation is not expressly disclosed, the modification of Giger's ANN in view of Nishikawa, would suggest a correlation is made to eliminate the use of redundant inputs, such as a patients age.];
- ranking each feature measure in the reduced set of feature measures [Nishikawa discloses that each feature is given a weight for use in the ANN's evaluation (col. 20 lines 8-11 and 30-33). This weight is essentially a way of ranking the features. Those features of higher ranking would be given greater weight.]; and
- selecting a highest ranked feature measure, and adding additional feature measures, based on a descending ranking, until the adding of the additional feature measures no longer provides additional useful information [In one embodiment pertaining to the classification of microcalcifications, Nishikawa discloses ranking the eight input features and no additional features (col. 19 lines 54-67). These eight input features are each given weights and thus are the eight highest ranked features (col. 20 lines 30-33). Therefore, Nishikawa teaches that additional features, those other than the eight identified, no longer provide additional information.].

It would have been obvious to one of ordinary skill in the art to modify Giger to alternatively use Nishikawa's ANN. It is conventional in the art to use ANNs for classification of extracted features and it is known that different ANNs offer different advantages, such as the speed of diagnosis. Additionally, one of ordinary skill in the art would recognize that the algorithm used by Nishikawa could be adopted for determination of bone fractures by using a different training set.

Art Unit: 2624

10. Claims 47-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishikawa in view of Giger and Sones.

Regarding Claim 47: Nishikawa discloses a method for detecting lung disease, the method comprising:

- utilizing a soft-tissue image from a dual or multiple energy image set [Figures 1 and 6B. Exposure X is a soft tissue image of a breast obtained in the image acquisition step (10) (col. 9 lines 65-67).];
- selecting a region of interest within the soft-tissue image to search for an indication of disease [The region of interest selected is the breast (col. 9 line 67).];
- segmenting the region of interest from a background of the soft-tissue image [Figure 1. The ROI, in this case the breast, is segmented from a background in step 20 (col. 8 lines 35-39).];
- identifying a candidate region within the bone image which correlates to the region of interest in the soft-tissue image [The difference between exposures X and X' yield the bone image (col. 10 lines 4-5). The microcalcification in this bone image is then discovered and its radiation contrast is determined (col. 10 lines 3-4).];
- extracting features from the candidate region in the bone image [Features of a microcalcification, which is the candidate region are measured (col. 17 lines 7-8).]; and,
- classifying the region of interest in the soft-tissue image as a candidate for soft-tissue disease utilizing the features extracted from the bone image [Figure 1. The ANN (50) inputs the features to classify the region of interest, in this case a microcalcification, as either malignant or benign (col. 7 line 63 – col. 8 line 2).].

Nishikawa does not disclose the details of the image set from which the soft tissue image is selected. However, Giger discloses a method for computer aided processing of dual or multiple energy images, the method comprising:

- employing a data source, the data source including a dual or multiple energy image set, the image set comprising a high energy image, a low energy image, a bone image, and a soft tissue image [Figure 22 illustrates two methods of obtaining dual energy radiographic images (col. 7 lines 47-49). The processing circuit receives dual energy images including high energy images, low energy images, “bone-cancelled” (soft-tissue) images, and “soft-tissue-cancelled” (bone) images (col. 7 lines 43-51).];

It would have been obvious to one of ordinary skill in the art to modify Nishikawa to select a soft tissue image from the image set defined by Giger. One would have been motivated to make this modification because it is well known in the art to obtain a soft tissue image from high and low energy images.

Giger also discloses employing a data source including a dual or multiple energy image set. Giger does not disclose the image set being arranged to allow the computer aided processing to be performed once by incorporating

Art Unit: 2624

features from all images of the image set. However, Sones discloses a diagnostic scanner (Figure 1, A) for obtaining a high energy image (Figure 1, V) and low energy image (Figure 1, U). As shown in Figure 1, these images are stored separately. Then from these images a soft tissue image (col. 6 lines 25-29) and a bone image (col. 7 lines 30-33) are formed and stored in separate memories (Figure 1, 42 and 52 respectively). Therefore, Sones teaches that all four images of the image set are available for computer aided processing. It would have been obvious to one of ordinary skill in the art to modify Giger with Sones to capture and store both the low energy image and high energy image and to create and store a soft tissue image and bone image, such that the image set is available for processing at the data source. In this manner, the diagnostic procedures of Giger would then just access the desired image from the respective memory. One would have been motivated to make this modification because it may be desirable to look back at the original unprocessed images. Additionally, it would have been desired to have the image set available in case the diagnostic procedures failed or were ruled inaccurate. In this case, the image set could be used again or by another diagnostic procedure to confirm the results of the initial diagnosis.

Regarding Claim 48: Nishikawa discloses the method of claim 47, wherein identifying a disease in the soft-tissue image comprises identifying a solitary pulmonary nodule or lesion, and wherein the features extracted from the bone-image are indicative of calcification of the nodule, the method further comprising utilizing the bone-image calcification features to classify the region of interest in the soft-tissue image as probably benign [The analogous arguments in claim 47 are applicable to claim 48. Although the steps in claim 47 are with respect to microcalcifications in breast images, these steps are also applicable to identifying lesions in lungs to diagnose lung diseases (col. 4 lines 40-46).].

Regarding Claim 50: Nishikawa discloses the method of claim 47 further comprising reporting at least one of the features using a marker on a display of each image within the dual or multiple energy image set where the at least one feature is located and displaying a single image which incorporates all markers from each image within the dual or multiple energy image set [Figure 30. The markers (740 and 750) from each image are shown together (col. 37 lines 34-47).].

Regarding Claim 51: Nishikawa discloses the method of claim 50 further comprising displaying a single image which incorporates markers uniquely indicative of results from the soft-tissue image that have been further classified based on results from the bone-image [Figure 30. The blue arrows indicate microcalcifications while the red arrows indicate masses (col. 37 lines 41-47).].

Conclusion

Art Unit: 2624

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick L Edwards whose telephone number is (571) 272-7390. The examiner can normally be reached on 8:30am - 5:00pm M-F.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhavesh Mehta can be reached on (571) 272-7453. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick L Edwards

Art Unit 2624

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